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ATTORNEY DOCKET NO.: 2002834-0232 (Bacterial Delivery DIV2)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Caplan  
Serial No.: 10/728,323  
Filing Date: December 4, 2003  
Title: MICROBIAL DELIVERY SYSTEM  
Examiner: Huynh  
Art Unit: 1644

Mail Stop: Amendments  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

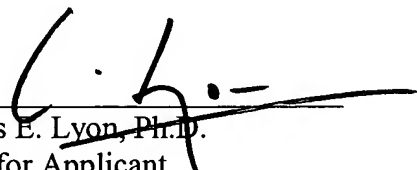
TRANSMITTAL LETTER

Enclosed are the following documents:

1. Form PTO-1449 (1 pages);
2. Supplemental Information Disclosure Statement (5 pages);
3. Transmittal Letter (1 page); and
4. Return Postcard.

If any additional fees are required to be paid or if any overpayment has been made, please charge same to Deposit Account No. 03-1721.

Respectfully submitted,

  
Charles E. Lyon, Ph.D.  
Agent for Applicant  
Registration No. 56,630

CHOATE, HALL & STEWART, LLP  
Exchange Place  
53 State Street  
Boston, MA 02109  
(617) 248-5000  
(617) 248-4900  
Dated: 7-6-05

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**Certificate of Mailing**

I certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to Mail Stop: Amendments, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Date

Signature

7-6-05 Sandra Saccocia

Sandra Saccocia

Typed or Printed Name of person signing certificate



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INFORMATION DISCLOSURE STATEMENT

Pursuant to the duty of disclosure under 37 CFR §§ 1.56, 1.97 and 1.98, Applicant requests consideration of this Information Disclosure Statement.

Type of Statement

The present Information Disclosure Statement is:

- ☐ An *original* Information Disclosure Statement; or
- ☒ A *supplemental* Information Disclosure Statement.

**Certificate of Mailing**

I certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

7-6-05 Sandra Saccoccia  
Date Signature

Sandra Saccoccia  
Name of Person Signing

Compliance with 37 CFR § 1.97

The present Information Disclosure Statement is being filed:

- ☒ Pursuant to 37 CFR § 1.97(b); no fee or certification is required:
- ☐ Within three months of the filing date of a national application other than a continued prosecution application under § 1.53(d);
  - ☐ Within three months of the date of entry of the national stage as set forth in § 1.491 in an international application;
  - ☒ Before the mailing of a first Office action on the merits; or
  - ☐ Before the mailing of a first Office action after the filing of a request for continued examination under § 1.114.
- ☐ Pursuant to 37 CFR § 1.97(c) after the dates listed above but before the mailing date of any of a final action under § 1.113, a notice of allowance under § 1.311, or an action that otherwise closes prosecution in the application; Applicant hereby *either*:
- ☐ Certifies that *either*:
    - ☐ each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement; or
    - ☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual

designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement; or

☐ Includes herewith the fee set forth in § 1.17(p),

☐ Pursuant to 37 CFR § 1.97(d), after the mailing date of any final action under § 1.113, a notice of allowance under § 1.311, or an action that otherwise closes prosecution in the application; Applicant hereby *both*:

☐ Certifies that *either*:

☐ each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement; or

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement; and

☐ Includes herewith the fee set forth in § 1.17(p).

Content of the Information Disclosure Statement

Applicant hereby makes of record in the above-identified application the reference(s) listed on the attached form PTO-1449 (modified). The order of presentation of the references should not be construed as an indication of the importance of the references.

Applicant includes copies of references as indicated below:

- ☐ A copy of each cited reference not indicated with an asterisk is included;
- ☒ Copies of references indicated with an asterisk on the attached form PTO-1449 are not included pursuant to 37 CFR § 1.98(d) because they were previously provided to the United States Patent Office in an Information Disclosure Statement that complies with 37 CFR § 1.98(a)-(c) and was submitted in the following patent application that is relied upon in the present case for an earlier effective filing date under 35 USC § 120:

Serial Number	Filing Date	Status
09/731,375	December 6, 2000	Published

- ☐ Copies of English translations of one or more non-English references are included.

Applicant hereby makes the following additional information of record in the above-identified application:

Applicant certifies that the Information Disclosure Statement *either*:

- ☒ Does not contain non-English language citations;
- ☐ Includes one or more translations of a non-English citation; or
- ☐ Does contain non-English language citations, of which the following is a concise explanation:

Remarks

The submission of this Information Disclosure Statement should not be construed as a representation that a search has been made.

The submission of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in § 1.56(b) .

The submission of this Information Disclosure Statement shall not be construed as a representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 USC §102.

It is respectfully requested that:

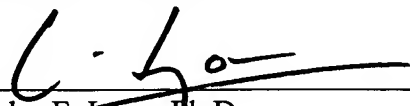
1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;
2. The enclosed form PTO-1449 be signed by the Examiner to evidence that the cited patent(s) and publication(s) has (have) been fully considered by the Patent and Trademark Office during the examination of this application; and
3. The citations for the patent(s) and publication(s) be printed on any patent which issues from this application.

Notwithstanding any statements by Applicants, the Examiner is urged to form his or her own conclusions regarding the relevance of the cited reference(s).

Dated:

1-17-05

Respectfully submitted,

  
\_\_\_\_\_  
Charles E. Lyon, Ph.D.  
Agent for Applicant  
Registration No. 56,630

CHOATE, HALL & STEWART, LLP  
Exchange Place  
53 State Street  
Boston, Massachusetts 02109  
(617) 248-5000  
(617) 248-4000



PTO-1449 (REV. 8-83)  <b>SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT</b> <i>(Use several sheets if necessary)</i>	U.S. Department of Commerce Patent and Trademark Office	ATTY. DOCKET: 2002834-0232	IN RE APPLICATION NO.: 10/728,323
	APPLICANT: Caplan		
	FILING DATE: December 4, 2003	GROUP: 1644	

#### U.S. PATENT DOCUMENTS

Examiner's Initials	U.S. Patent No.	Applicant	Issue Date	Class	Subclass
	*6,486,311	Burks, Jr. et al.	November 26, 2002	536	23.6
	*5,328,991	Kuo	July 12, 1994	530	403

#### U.S. PATENT APPLICATIONS

Examiner's Initials:	Serial Number:	Applicant:	Publication Date:	Group:	Art Unit:

#### FOREIGN PATENT DOCUMENTS

Examiner's Initials	Document No.	Country	Date	Translation	
				Yes	No
	*EP 0 819 763	Europe	21 January 1998		

#### OTHER DOCUMENTS

Examiner's Initials	Citation (Including Author, Title, Date, Pertinent Pages, Etc.)
	*Chatel, et al., "Various Factors (Allergen Nature, Mouse Strain, CpG/Recombinant Protein Expressed) Influence the Immune Response Elicited by Genetic Immunization", <i>Allergy</i> , <b>58</b> : 641-647, 2003.
	*Evans, et al., "Non-Replicating Oral Whole Cell Vaccine Protective Against Enterotoxigenic Escherichia Coli (ETEC) Diarrhea: Stimulation of Anti-CFA (CFA/I) and Anti-Enterotoxin (Anti-LT) Intestinal IgA and Protection Against Challenge with ETEC Belonging to Heterologous Serotypes", <i>FEMS Microbiology Immunology</i> , <b>47</b> : 117-126, 1988.
	*Gotlieb, "Scientists Develop Vaccine Strategy for Peanut Allergy", <i>BMJ</i> , <b>318</b> : 894, 1999.
	*Vrtala, et al., "Conversion of the Major Birch Pollen Allergen, Bet v 1, into Two Nonanaphylactic T Cell Epitope-Containing Fragments", <i>J. Clin. Invest.</i> <b>99</b> (7): 1673-1681, 1997.

EXAMINER	DATE CONSIDERED
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EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line

<b>PTO-1449</b>  <b>(REV. 8-83)</b>  <b>SUPPLEMENTAL</b> <b>INFORMATION DISCLOSURE STATEMENT</b> <i>(Use several sheets if necessary)</i>	U.S. Department of Commerce Patent and Trademark Office	ATTY. DOCKET: 2002834-0232	IN RE APPLICATION NO.: 10/728,323
		APPLICANT: Caplan	
		FILING DATE: December 4, 2003	GROUP: 1644
through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.			

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